UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NORA GIOIA AND MICHAEL GIOIA, Plaintiffs, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; MERCK & CO. INC., Defendants.	**Case No.:** **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs, by their attorneys, **ANAPOL WEISS,** upon information and belief, at all times hereinafter mentioned, allege as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceed $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiffs resides.

NATURE OF THE CASE

2. This action is brought on behalf of Plaintiff, NORA GIOIA, who used prescription brand Nexium for treatment of Plaintiff's gastroesophageal reflux disease.

3. Plaintiff seeks compensatory damages as a result of Plaintiff's use of Nexium, which has caused Plaintiff to suffer and continue to suffer from Stomach Cancer, Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for

lifelong medical treatment, monitoring and/or medications, and fear of developing any of additional health consequences.

4. Defendants, AstraZeneca Pharmaceuticals LP, AstraZeneca LP, and Merck & Co. Inc. (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Nexium.

5. When warning of safety and risks of Nexium, Defendants negligently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the "FDA"), the Plaintiff's treating physicians, and the public in general, that Nexium had been tested and was found to be safe and/or effective for its indicated use in treating gastroesophageal reflux disease and peptic disorders.

6. Defendants concealed their knowledge of Nexium's defects, specifically the fact that it causes gastric carcinoma and kidney injuries, from Plaintiff's treating physicians, hospitals, pharmacies, the FDA, the public in general and/or the medical community.

7. These representations were made by Defendants with the intent of defrauding and deceiving the Plaintiff's physicians, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Nexium for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

8. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer serious and dangerous side effects including inter alia stomach cancer, chronic kidney disease, as well as other severe and personal injuries which are permanent and lasting in nature,

physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any additional health consequences.

9. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of Nexium, which has caused Plaintiff to suffer from stomach cancer, chronic kidney disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTIES

10. Plaintiff, NORA GIOIA, is a citizen of the United States of America, and is a citizen of Maryland.

11. Plaintiff, NORA GIOIA, was born on June 29, 1961.

12. Plaintiff, NORA GIOIA, first began using prescription brand Nexium in or about July 2009, and Plaintiff used prescription brand Nexium up through July 2013.

13. As result of Plaintiff's ingestion of Defendants' Nexium, Plaintiff NORA GIOIA has suffered and continues to suffer from stomach cancer which was diagnosed on or about July 2013, as well as any and all of its sequelae and attendant pain, suffering, and emotional distress.

14. Plaintiff's ingestion of Defendants' Nexium also caused Plaintiff, NORA GIOIA, to suffer and continue to suffer from Chronic Kidney Disease, as well as any and all of its attendant pain, suffering, and emotional distress.

15. The injuries and damages sustained by Plaintiff, NORA GIOIA, were caused by Defendants' Nexium and their unlawful conduct with respect to its design, manufacture, marketing and sale.

16. Plaintiff, MICHAEL GIOIA, is a citizen of the United States of America, and is a resident of the State of Maryland and is the lawful spouse of NORA GIOIA.

17. Defendant AstraZeneca Pharmaceuticals, LP is, and at all times relevant to this action was, a limited partnership organized under the laws of the State of Delaware with its headquarters and principal place of business located at 1800 Concord Pike, Wilmington, Delaware.

18. AstraZeneca Pharmaceutical LP's general partner is AstraZeneca AB, a corporation incorporated under the laws of the nation of Sweden with its principal place of business in Sweden. AstraZeneca Pharmaceutical LP's sole limited partner is Zeneca Inc., which is a corporation incorporated under the laws of the State of Delaware with its principal place of business in Delaware.

19. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals, LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

20. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals, LP was present and doing business in the states of New Jersey and Maryland.

21. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business in the states of New Jersey and Maryland and derived substantial revenue from such business.

22. Upon information and belief, at all times relevant hereto, Defendant AstraZeneca Pharmaceuticals, LP expected or should have expected that its acts would have consequences

within the United States of America, and the states of New Jersey and Maryland.

23. Defendant AstraZeneca LP is, and at all times relevant to this action was, a limited partnership organized under the laws of the State of Delaware with its headquarters and principal place of business located at 1800 Concord Pike, Wilmington, Delaware.

24. Defendant AstraZeneca LP's sole general partner is AstraZeneca Pharmaceuticals LP. Defendant AstraZeneca LP has no limited partners. AstraZeneca Pharmaceutical LP's general partner is AstraZeneca AB, a corporation incorporated under the laws of the nation of Sweden with its principal place of business in Sweden. AstraZeneca Pharmaceutical LP's sole limited partner is Zeneca Inc., a corporation incorporated under the laws of the State of Delaware with its principal place of business in Delaware.

25. Defendant AstraZeneca LP is the holder of approved New Drug Applications ("NDA") 21-153 for Nexium (Esomeprazole Magnesium), and it manufactures and markets Nexium (Esomeprazole Magnesium) in the United States.

26. Upon information and belief, at all times relevant hereto Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Nexium products.

27. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in the states of New Jersey and Maryland.

28. Upon information and belief, at all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business in the states of New Jersey and Maryland, and derived substantial revenue from such business.

29. Upon information and belief, at all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United

States of America, and the states of New Jersey and Maryland.

30. Upon information and belief, each AstraZeneca Defendant was the agent and employee of each other AstraZeneca Defendant, and in doing the things alleged was acting within the course and scope of such agency and employment and with each other AstraZeneca Defendant's actual and implied permission, consent, authorization, and approval.

31. In 1982, the AstraZeneca Defendants entered a joint venture with Defendant Merck to design and develop the first proton pump inhibitor.

32. The result of this joint-venture was the development of omeprazole and later, esomeprazole, which were ultimately marketed and sold under the brand names Prilosec and Nexium.

33. In anticipation of the expiration of the patent for prescription Prilosec, the AstraZeneca Defendants launched an internal program called Operation Shark Fin for the purpose of developing a second PPI Product in order to capitalize on the market for PPI Products. The result of Operation Shark Fin was the development of Nexium (esomeprazole).

34. In December 1999, Defendant AstraZeneca Pharmaceutical LP submitted its first NDA for a Nexium product, NDA 021153, to the FDA for approval to market Nexium in the United States.

35. Defendant Merck & Co. Inc. d/b/a Merck, Sharp & Dohme Corporation (hereinafter "Defendant Merck") is and, all times relevant to this action, has been a New Jersey corporation having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

36. In 1982, Defendant Merck entered into an agreement with the AstraZeneca Defendants, under the terms of which Defendant Merck developed and marketed the AstraZeneca Defendants' products, including Nexium and Prilosec products, under a royalty-bearing license.

37. In 1993, Merck's total sales of the AstraZeneca Defendants' products reached a level that triggered the first step in the establishment of a joint venture business (the "Joint Venture") in which Defendant Merck and the AstraZeneca Defendants each owned a 50% share. This Joint Venture, formed in 1994, was called Astra Merck Inc. and was responsible for the sale of Prilosec and other of the AstraZeneca Defendants' products.

38. Until 2014, Defendant Merck had a contractual and ownership interest in the Joint Venture. Through these interests, between 2009 and 2014, Defendant Merck earned at least $7 billion, based on the sales of prescription and over-the-counter formulations of Nexium.

39. Defendant Merck currently has, and will continue to have until 2018, a financial interest in prescription and over-the-counter formulations of Nexium.

40. As a part of their business and at all relevant times, Defendant Merck has been and is involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription and over-the-counter formulations of Nexium.

41. Defendant Merck, through the Joint Venture, also designed, researched, manufactured, tested, advertised, marketed, sold and distributed Nexium.

42. Defendant Merck has had a contractual, ownership and financial interest in the following FDA approved forms of Nexium: Delayed-Release Capsule Pellets, NDA 021153; Delayed-Release Oral Suspension, NDAs 02195 and 022010; and Intravenous Injectable Solution, NDA 021689.

43. Defendant Merck manufactured and marketed Nexium in the United States.

44. Defendant Merck has transacted and conducted business related to Nexium in each of the States and Territories of the United States.

45. Defendant Merck has derived substantial revenue from Nexium in each of the

States and Territories of the United States.

46. Defendant Merck has expected or should have expected its acts to have consequence within each of the States and Territories of the United States and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Nexium.

47. Defendants AstraZeneca LP, AstraZeneca Pharmaceuticals LP and Merck shall herein be collectively referred to as "Defendants."

FACTUAL BACKGROUND

48. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff NORA GIOIA suffering stomach cancer and chronic kidney disease caused by Plaintiff's ingestion of the proton pump inhibitor, Nexium.

49. Upon information and belief, the Defendants began marketing and selling prescription brand Nexium in 2001.

50. Upon information and belief, Plaintiff began taking prescription brand Nexium in or about 2009.

51. At all relevant times, Defendants heavily marketed Nexium and to treat peptic disorders, including but not limited to gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

52. Defendants' marketing of Nexium included advertisements, press releases, web site publications, sales representative pitches and other communications.

53. Materials including advertisements, press releases, webs site publications and other communications regarding Nexium are part of the labeling of the drug and could be altered by Defendants without prior FDA approval.

54. Proton pump inhibitors ("PPIs"), including Defendants' Nexium, are one of the most commonly prescribed medications in the United States.

55. More than 15 million Americans used prescription PPIs in 2013, costing more than $10 billion.

56. However, it has been estimated that between 25% and 70% of these prescriptions have no appropriate indication.

57. Up to 70% of PPIs may be used inappropriately for indications or durations that were never tested or approved.

58. Further, 25% of long-term PPI users could discontinue therapy without developing any symptoms.

59. The AstraZeneca Defendants sold Nexium with National Drug Code (NDC) numbers 00186-5020; 00186-5022; 00186-5040; 00186-5042; 0186-4010; 0186-4020 and 00186-4040.

60. Nexium (Esomeprazole Magnesium), is a PPI that works by reducing hydrochloric acid in the stomach.

61. During the period in which Nexium has been sold in the United States, hundreds of reports of injuries, including stomach cancer and acute and chronic kidney disease, have been submitted to the FDA in association with ingestion of Nexium, and other PPIs.

62. Defendants have had notice of serious adverse health outcomes regarding stomach cancer and acute and chronic kidney disease associated with their Nexium through case reports, clinical studies and post-market surveillance.

63. As such, these numerous reports of stomach cancer and kidney injuries put Defendants on notice as to the excessive risks of stomach cancer and kidney injuries related to

the use of Nexium.

64. Several observational studies have linked PPI use, including Nexium use, to serious adverse health outcomes, including stomach cancer, chronic kidney disease, acute interstitial nephritis and acute kidney injury.

65. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a petition with the U.S. FDA to add black box warnings and other safety information concerning several risks associated with PPIs, including acute interstitial nephritis.

66. In December of 2014, the labels of prescription PPIs were updated to read:

> *Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [Brand] if acute interstitial nephritis develops.*

67. A study from 2015 shows that acute kidney injuries increased 250% in elderly patients that were newly prescribed PPIs. The acute kidney injuries occurred within 120 days of the patients staring the PPIs.

68. If left untreated, acute interstitial nephritis can lead to chronic kidney disease renal failure, dialysis, kidney transplant and/or death.

69. In the early stages of chronic kidney disease, patients may have few signs or symptoms. Chronic Kidney Disease may not become apparent until kidney function is significantly impaired.

70. Treatment for chronic kidney disease focuses on slowing the progression of kidney damage, usually by attempting to control the underlying cause. Chronic kidney disease can progress to end-stage kidney failure, which can be fatal absent artificial filtering, dialysis or a kidney transplant. Early treatment is often the key to avoiding the most negative outcomes.

71. Recent studies have shown the long-term use of PPIs, including Nexium, was independently associated with a 20% to 50% higher risk of chronic kidney disease, after adjusting for several potential confounding variables, including demographics, socioeconomic status, clinical measurements, prevalent co-morbidities, and concomitant use of medications.

72. In at least one recent study, the use of PPIs for ***any*** period of time, was shown to increase the risk of chronic kidney disease by 10%.

73. A meta-analysis that was recently published in 2017 indicated that there was a significantly increased risk of chronic kidney disease associated with use of PPIs in the absence of intervening acute kidney injury.

74. Currently, the Nexium product labeling does not contain any warning regarding the increased risk of chronic kidney disease.

75. In addition, a study by Lai, et al., published by GUT in April 2018, found that long-term proton pump inhibitors increased the risk of gastric cancer development. Shih-Wei Lai, Hsueh-Chou Lai, Cheng-Li Lin and Kuan-Fu Liao. *Proton Pump Inhibitors and Risk of Gastric Cancer in a Case-Control Study*. Gut (2018).

76. A 2018 study by Cheung also found an association among long-term proton pump inhibitors and risk of gastric cancer development. Cheung, KS, Chan, EW, Wong, AYS, Chen, L, Wong, ICK, Leung, WK. *Long-term Proton Pump Inhibitors and Risk of Gastric Cancer Development after Treatment for* Helicobacter Pylori: *A Population-Based Study*. Gut (2018).

77. Other recent articles, such as Brusselaers and Lai, found a similar risk of gastric cancer development with proton pump inhibitor use. Brusselaers N, Wahlin, K, Engstrand, L, et al. *Maintenance Therapy with Proton Pump Inhibitors and Risk of Gastric Cancer: A Nationwide Population-based Cohort Study in Sweden*. BMJ Open (2017); Lai, SW, Liao KF, Lai HC, Lin

CL, Sung FC. *Use of Proton Pump Inhibitors Correlates with Increased Risk of Colorectal Cancer in Taiwan.* Asia Pac. J. Clin. Oncol. (2013);

78. There are other studies, and articles in the medical community, as well as other evidence that associates PPIs, including Nexium, with stomach (gastric) cancer and CKD.

79. To date, Defendants' prescription Nexium lacks detailed risk information for stomach cancer and chronic kidney disease, despite science stating otherwise.

80. Defendants knew or should have known of the risk of stomach cancer or chronic kidney disease based on the data available to them or that could have been generated by them, including but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

81. Despite their knowledge of the risks of stomach cancer and chronic kidney disease associated with their proton pump inhibitor, Nexium, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Nexium did not pose any risks of stomach cancer or chronic kidney disease. They promoted and marketed Nexium as safe and effective for persons such as Plaintiff NORA GIOIA throughout the United States, including New Jersey and Maryland.

82. Defendants knew of the significant risk of stomach cancer and chronic kidney disease that could result from Nexium use, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff's physician or the medical community in a timely manner.

83. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with Nexium including, but not necessarily limited to, long term usage

and the cumulative effects of long term usage.

84. In omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium in order to induce its purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff. This conduct is fraudulent, unfair, and unlawful.

85. Despite clear knowledge that Nexium causes a significantly increased risk of stomach cancer, chronic kidney disease, acute kidney injuries, Defendants continued to market and sell Nexium without warning consumers or healthcare providers of the significant risks of stomach cancer, chronic kidney disease and acute kidney injuries.

86. Even if used as directed, persons who ingested Nexium, such as the Plaintiff NORA GIOIA, have been exposed to significant risks stemming from unindicated and/or long-term usage.

87. Consumers, including Plaintiff NORA GIOIA, and Plaintiff's physicians relied on the Defendants' false representations and were misled as to Nexium's safety.

88. Had the Plaintiff NORA GIOIA known of the risks of stomach cancer and chronic kidney disease associated with Defendants' Nexium, Plaintiff would not have used Defendants' Nexium.

89. At all relevant times, Plaintiff NORA GIOIA had alternative safer methods for treating peptic disorders that provided the same benefits but acted through a different mechanism and were not associated with stomach cancer or chronic kidney disease.

90. One alternative was H2 antagonists, also called H2 blockers, a class of medications that block the action of histamine at the histamine H2 receptors of the parietal cells in the stomach. The use of H2 receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with stomach cancer or chronic kidney disease.

91. As a result of Defendants' action and inactions as outlined herein, Plaintiff was injured due to Plaintiff's ingestion of Nexium, which caused Plaintiff and continues to cause Plaintiff to suffer from chronic kidney disease, stomach cancer and any and all of its sequelae.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

92. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

93. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Nexium into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

94. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Nexium into interstate commerce in that Defendants knew or should have known that using Nexium could proximately cause Plaintiffs' injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Nexium. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

(a) Failure to adequately warn Plaintiff, NORA GIOIA, and Plaintiff's physicians of the known or reasonably foreseeable danger that plaintiff would suffer a serious injury or death by ingesting Nexium;

(b) Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer

a serious injury or death by ingesting Nexium in unsafe doses;

(c) Failure to use reasonable care in testing and inspecting Nexium so as to ascertain whether or not they were safe for the purpose for which they were designed, manufactured and sold;

(d) Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Nexium;

(e) Failure to use reasonable care in the process of manufacturing Nexium in a reasonably safe condition for the use for which they were intended;

(f) Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Nexium in unsafe doses; and

(g) Such further acts and/or omissions that may be proven at trial.

95. The above-described acts and/or omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

96. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Nexium without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing Nexium without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not Nexium was safe for use; in that Defendants herein knew or should have known that Nexium was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling Nexium without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Nexium;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Nexium;

(g) Failing to test Nexium and/or failing to adequately, sufficiently and properly test Nexium.

(h) Negligently advertising and recommending the use of Nexium without sufficient knowledge as to their dangerous propensities;

(i) Negligently representing that Nexium was unsafe;

(j) Negligently designing Nexium in a manner which was dangerous to their users;

(k) Negligently manufacturing Nexium in a manner which was dangerous to their users;

(l) Negligently producing Nexium in a manner which was dangerous to their users;

(m) Negligently assembling Nexium in a manner which was dangerous to their users;

(n) Concealing information from the Plaintiff in knowing that Nexium was unsafe, dangerous, and/or non-conforming with FDA regulations.

97. Defendants under-reported, underestimated and downplayed the serious dangers of Nexium.

98. Defendants negligently compared the safety risk and/or dangers of Nexium with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

99. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Nexium in that they:

(a) Failed to use due care in designing and manufacturing Nexium so as to avoid the aforementioned risks to individuals when Nexium was used for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the uses of Nexium;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Nexium;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Nexium;

(e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Nexium;

(g) Failed to warn Plaintiff, prior to actively encouraging the sale of Nexium, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

(h) Were otherwise careless and/or negligent.

100. Despite the fact that Defendants knew or should have known that Nexium caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Nexium to consumers, including the Plaintiff.

101. Defendants knew or should have known that consumers such as the Plaintiff, NORA GIOIA, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

102. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff, NORA GIOIA suffered and/or will continue to suffer.

103. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, chronic kidney disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

104. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

105. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)

106. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

107. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Nexium as hereinabove described that was used by the Plaintiff.

108. That Nexium was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

109. At those times, Nexium was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

110. The Nexium designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Nexium.

111. The Nexium designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants manufacturers and/or suppliers, they were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect.

112. At all times herein mentioned, Nexium was in a defective condition and unsafe, and Defendants knew or had reason to know that said products were defective and unsafe, especially when used in the form and manner as provided by the Defendants.

113. Defendants knew or should have known that at all times herein mentioned its Nexium was in a defective condition and were and are inherently dangerous and unsafe.

114. At the time of the Plaintiff's uses of Nexium, Nexium was being used for the purposes and in a manner normally intended for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

115. Defendants with this knowledge voluntarily designed Nexium in a dangerous condition for use by the public, and in particular the Plaintiff.

116. Defendants had a duty to create products that were not unreasonably dangerous for its normal, intended use.

117. Defendants created products unreasonably dangerous for their normal, intended use.

118. The Nexium designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that Nexium left the hands of Defendants in a defective condition and were unreasonably dangerous to their intended users.

119. The Nexium designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Nexium was manufactured.

120. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

121. The Plaintiff could not, by the exercise of reasonable care, have discovered Nexium's defects herein mentioned and perceived their danger.

122. Nexium was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, stomach cancer, kidney injuries, as well as other severe and

personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

123. Nexium was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

124. Nexium was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, stomach cancer and kidney injuries, as well as other severe and permanent health consequences from Nexium, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Nexium.

125. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Nexium.

126. Defendants' defective design, manufacturing defect, and inadequate warnings of Nexium were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

127. That said defects in Defendants' drug Nexium was a substantial factor in causing Plaintiff's injuries.

128. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, chronic kidney disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and

mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

129. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

130. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

131. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

132. Defendants expressly warranted that Nexium was safe and well accepted by users.

133. Nexium does not conform to these express representations because Nexium is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

134. Plaintiff did rely on the express warranties of the Defendants herein.

135. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Nexium in recommending, prescribing, and/or dispensing Nexium.

136. The Defendants herein breached the aforesaid express warranties, as their drugs Nexium was defective.

137. Defendants expressly represented to Plaintiff's physicians, healthcare providers, and/or the FDA that Nexium was safe and fit for use for the purposes intended, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects it did produce were accurately reflected in the warnings and that they were adequately tested and fit for their intended use.

138. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Nexium was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

139. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, chronic kidney disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

140. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Nexium drug.

141. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

142. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

143. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

144. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Nexium and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Nexium for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

145. At the time Defendants marketed, sold, and distributed Nexium for use by Plaintiff, Defendants knew of the uses for which Nexium was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

146. The Defendants impliedly represented and warranted to the users of Nexium and their physicians, healthcare providers, and/or the FDA that Nexium was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

147. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Nexium was unsafe, unreasonably dangerous, improper, not of merchantable

quality, and defective.

148. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

149. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Nexium was of merchantable quality and safe and fit for its intended use.

150. Nexium was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

151. The Defendants herein breached the aforesaid implied warranties, as their drugs Nexium was not fit for its intended purposes and uses.

152. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, chronic kidney disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

153. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

154. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FIFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUDULENT MISREPRESENTATION)

155. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

156. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said product, Nexium had been tested and were found to be safe and/or effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

157. That representations made by Defendants were, in fact, false.

158. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

159. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Nexium, for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

160. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Nexium, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

161. In reliance upon said representations, the Plaintiff was induced to and did use Nexium, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

162. Said Defendants knew and were aware or should have been aware that Nexium had not been sufficiently tested, were defective in nature, and/or that they lacked adequate and/or sufficient warnings.

163. Defendants knew or should have known that Nexium had a potential to, could, and would cause severe and grievous injury to the users of said products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

164. Defendants brought Nexium to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

165. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, chronic kidney disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

166. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical and/or hospital care, attention, and services.

167. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SIXTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUDULENT CONCEALMENT)

168. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

169. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Nexium for its intended use.

170. Defendants knew or were reckless in not knowing that its representations were false.

171. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

(a) that Nexium was not as safe as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

(b) that the risks of adverse events with Nexium were higher than those with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

(c) that the risks of adverse events with Nexium were not adequately tested and/or known by Defendants;

(d) that Defendants were aware of dangers in Nexium, in addition to and above and beyond those associated with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

(e) that Nexium were defective, and that it caused dangerous side effects, including but not limited to stomach cancer and chronic kidney disease;

(f) that patients needed to be monitored more regularly than normal while using Nexium;

(g) that Nexium was manufactured negligently;

(h) that Nexium was manufactured defectively;

(i) that Nexium was manufactured improperly;

(j) that Nexium was designed negligently;

(k) that Nexium was designed defectively; and

(l) that Nexium was designed improperly.

172. Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Nexium, including but not limited to the heightened risks of stomach cancer and chronic kidney disease.

173. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Nexium, including the Plaintiff, in particular.

174. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Nexium was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare providers into reliance, continued use

of Nexium, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Nexium and/or use the product.

175. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Nexium, as set forth herein.

176. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

177. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, chronic kidney disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

178. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

179. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENT MISREPRESENTATION)

180. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

181. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, Nexium, had been tested and found to be safe and effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

182. The representations made by Defendants were, in fact, false.

183. Defendants failed to exercise ordinary care in the representation of Nexium, while involved in their manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Nexium's high risks of unreasonable, dangerous side effects.

184. Defendants breached their duty in representing Nexium's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

185. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, chronic kidney disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

186. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

187. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

EIGHTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUD AND DECEIT)

188. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

189. Defendants conducted research and used Nexium as part of their research.

190. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that Nexium was safe and effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

191. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

192. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.

193. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

194. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug Nexium was safe and effective for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

195. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug Nexium carried the same risks, hazards, and/or dangers as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

196. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Nexium was not injurious to the health and/or safety of its intended users.

197. The information distributed to the public, the FDA, and the Plaintiffs, by Defendants intentionally included false representations that Nexium was as potentially injurious to the health and/or safety of its intended as other forms of treatment for treatment of peptic

disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

198. These representations were all false and misleading.

199. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Nexium was not safe as a means of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

200. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiffs, regarding the safety of Nexium, specifically but not limited to Nexium not having dangerous and serious health and/or safety concerns.

201. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiffs, regarding the safety of Nexium, specifically but not limited to Nexium being a safe means for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

202. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Nexium induces the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Nexium.

203. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiffs that

Nexium was fit and safe for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

204. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Nexium was fit and safe for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

205. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Nexium did not present serious health and/or safety risks.

206. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Nexium did not present health and/or safety risks greater than other oral forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

207. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

208. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including Plaintiff's respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or Plaintiff's

respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Nexium.

209. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Nexium to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

210. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Nexium by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Nexium.

211. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as Plaintiff's respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Nexium and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

212. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.

213. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Nexium.

214. That the Plaintiff and/or Plaintiff's respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

215. That at the time the representations were made, the Plaintiff and/or Plaintiff's respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Nexium.

216. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

217. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Nexium, Plaintiff would not have purchased, used and/or relied on Defendants' drug Nexium.

218. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

219. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, chronic kidney disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

220. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

221. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (LOSS OF CONSORTIUM ON BEHALF OF PLAINTIFF MICHAEL GIOIA)

222. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

223. Plaintiff, MICHAEL GIOIA was and is the lawful spouse of Plaintiff NORA GIOIA, and as such, was and is entitled to the comfort, enjoyment, society and services of his spouse.

224. As a direct and proximate result of the foregoing, Plaintiff MICHAEL GIOIA was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff.

225. NORA GIOIA, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. The Plaintiffs, NORA GIOIA and MICHAEL GIOIA's injuries and damages are permanent and will continue into the future. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

226. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

TENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT)

227. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

228. At all times relevant, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et. seq., prohibits "[the] act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise…" and declares such acts or practices as unlawful.

229. Defendants violated the New Jersey Consumer Fraud Act by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Nexium. Defendants communicated the purported benefits of Nexium while failing to disclose the serious and dangerous side effects related to the use of Nexium with the intent that consumers, including Plaintiff, and Plaintiff's healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Nexium, respectively.

230. As a result of violating the New Jersey Consumer Fraud Act, Defendants caused Plaintiff to be prescribed and to use Nexium, causing severe injuries and damages as previously described herein.

ELEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (PRODUCT LIABILITY –DESIGN DEFECT) (N.J.S.A. 2A:58C-1 *et seq*))

231. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

232. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed Nexium, including the Nexium used by Plaintiff, NORA GIOIA, was in a defective and unreasonably dangerous condition.

233. Defendants expected Nexium to reach, and it did in fact reach, Plaintiff without substantial change in the condition in which it was manufactured and sold by the Defendants.

234. At all times relevant hereto, Defendants' Nexium was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by the public and in particular, by Plaintiff.

235. At all times relevant to this action, Nexium, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by the Defendants, was defective in design and formulation in one or more of the following particulars:

(a) When placed in the stream of commerce, Nexium contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;

(b) When placed in the stream of commerce, Nexium was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer

would expect and more dangerous than other risks associated with the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

(c) Nexium was insufficiently tested;

(d) Nexium caused harmful side effects that outweighed any potential utility;

(e) Defendants were aware at the time Nexium was marketed that ingestion of Nexium would result in an increased risk of stomach cancer, acute kidney injury, chronic kidney disease and other injuries;

(f) Inadequate post-marketing surveillance; and/or

(g) There were safer alternative designs and formulations that were not utilized.

240. Nexium was defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.

241. Nexium, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in its design or formulation, in that it was unreasonably dangerous, and its foreseeable risks exceeded the alleged benefits associated with Nexium's design or formulation.

242. Nexium, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in design or formulation in that it posed a greater likelihood of injury than other proton-pump inhibitors and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

243. At all times relevant to this action, Defendants knew or had reason to know that Nexium was in a defective condition and was inherently dangerous and unsafe when used in the manner instructed, provided, and/or promoted by Defendants.

244. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and otherwise ensure that Nexium was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

245. When Defendants placed Nexium into the stream of commerce, they knew it would be prescribed to treat peptic disorders, and they marketed and promoted Nexium as safe for treating peptic disorders.

246. Plaintiff was prescribed, purchased, and used Nexium. Plaintiff used Nexium for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

247. Neither Plaintiff nor Plaintiff's health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with Nexium before Plaintiff's ingestion of Nexium.

248. The harm caused by Nexium far outweighed its benefit, rendering Nexium more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed Nexium to make it less dangerous. When Defendants designed Nexium, the state of the industry's scientific knowledge was such that a less risky design was attainable.

249. At the time Nexium left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Plaintiff suffered without

substantially impairing the reasonably anticipated or intended function of Nexium. This was demonstrated by the existence of other peptic disorder medications that had a more established safety profile and a considerably lower risk profile.

250. Defendants' defective design of Nexium was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Nexium. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of Nexium.

251. The defects in Nexium was substantial and contributing factors in causing Plaintiff's injuries. But for Defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

252. Due to the unreasonably dangerous condition of Nexium, Defendants are liable to Plaintiff.

253. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Nexium, including Plaintiff, with knowledge of the safety problems associated with Nexium, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

254. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered, and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent

conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

TWELFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS PRODUCTS LIABILITY – FAILURE TO WARN (N.J.S.A. 2A:58C-1 *et seq.*))

255. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

256. Defendants have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing Nexium. Through that conduct, Defendants knowingly and intentionally placed Nexium into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff, NORA GIOIA, who ingested it.

257. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released Nexium into the stream of commerce. In the course of this, Defendants directly advertised, marketed, and promoted Nexium to the FDA, health care professionals, Plaintiff, and other consumers, and therefore had a duty to warn of the risks associated with the use of Nexium.

258. Defendants expected Nexium to reach, and it did in fact reach, prescribing health care professionals and consumers, including Plaintiff and Plaintiff's prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

259. Nexium, as manufactured and/or supplied by Defendants, was defective due to inadequate warnings or instructions. Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

260. Nexium was defective and unsafe such that it was unreasonably dangerous when it left Defendants' possession and/or control, was distributed by Defendants, and ingested by Plaintiff. Nexium contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with Nexium, including the development of Plaintiff's injuries.

261. This defect caused serious injury to Plaintiff, who used Nexium for its intended purpose and in a reasonably anticipated manner.

262. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as are necessary to ensure Nexium did not cause users to suffer from unreasonable and dangerous risks.

263. Defendants negligently and recklessly labeled, distributed, and promoted Nexium.

264. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Nexium.

265. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held to the knowledge of an expert in the field.

266. Plaintiff could not have discovered any defects in Nexium through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

267. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that Nexium caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of Nexium, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

268. Nexium, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably and intended manner without knowledge of this risk of serious bodily harm.

269. Each of the Defendants knew or should have known that the limited warnings disseminated with Nexium were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

270. Defendants communicated to health care professionals, information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:

(a) disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of Nexium;

(b) continued to aggressively promote Nexium even after Defendants knew or should have known of the unreasonable risks from use;

(c) failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Nexium and the comparative severity of such adverse effects;

(d) failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with Nexium's capacity to cause its users to suffer;

(e) failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients who do not already suffer from renal impairment; and

(f) overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of Nexium.

271. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of Nexium.

272. Due to these deficiencies and inadequacies, Nexium was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.

273. Had Defendants properly disclosed and disseminated the risks associated with Nexium, Plaintiff would have avoided the risk of developing injuries as alleged herein.

274. The Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of Nexium and the risks associated with its use.

275. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered, and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

THIRTEENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (PRODUCT LIABILITY – MANUFACTURING DEFECT (N.J.S.A. 2A:58C-1 *et seq.*))

276. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

277. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium.

278. At all times material to this action, Nexium was expected to reach, and did reach, consumers in the States of, New Jersey, and throughout the United States, including Plaintiff, NORA GIOIA, without substantial change in the condition in which it was sold.

279. At all times material to this action, Nexium was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

(a) When placed in the stream of commerce, Nexium contained manufacturing defects which rendered the product unreasonably dangerous;

(b) The subject product's manufacturing defects occurred while the product was in the possession and control of Defendants;

(c) The subject product was not made in accordance with Defendants' specifications or performance standards; and/or

(d) The subject product's manufacturing defects existed before it left the control of Defendants.

280. As a direct and proximate result of the design defect and Defendants' misconduct set forth herein, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

FOURTEENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (PUNITIVE DAMAGES UNDER COMMON LAW, THE PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15 *et seq.*) AND THE PRODUCTS LIABILITY ACT (N.J.S.A. 2A:58C-1 *et seq.*))

281. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

282. Plaintiff is entitled to punitive damages because Defendants misrepresented and/or withheld information and materials from the FDA, the medical community and the public at large, including the Plaintiff, concerning the safety profile, and, more specifically the serious side effects and/or complications associated with Nexium.

283. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of Nexium, despite available information that Nexium was likely to cause serious side effects and/or complications.

284. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of Nexium, despite available information that Nexium was likely to cause serious side effects and/or complications.

285. Defendants' failure to provide the necessary materials and information to the FDA, as well as their failure warn physicians and consumers of the serious side effects and/or complications, was reckless and without regard for the public's safety and welfare.

286. Defendants were or should have been in possession of evidence demonstrating that Nexium causes serious side effects. Nevertheless, Defendant continued to market Nexium by providing false and misleading information with regard to safety and efficacy.

287. Defendants failed to provide the FDA, physicians and consumers with available materials, information and warnings that would have ultimately dissuaded physicians from prescribing Nexium to consumers, from purchasing and consuming Nexium, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Nexium.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

Dated: October 18, 2018

/s/ Tracy A. Finken

TRACY A. FINKEN, ESQ.
ANAPOL WEISS
1040 Kings Highway North, Suite 304
Cherry Hill, NJ 08034
Ph: (215)735-1130
Fax: (215)875-7701
Email: tfinken@anapolweiss.com

ATTORNEYS FOR PLAINTIFFS

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: October 18, 2018

/s/ Tracy A. Finken

TRACY A. FINKEN, ESQ.
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ATTORNEYS FOR PLAINTIFFS

JS 44 (Rev. 07/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Nora Gioia and Michael Gioia, w/h

DEFENDANTS
AstraZeneca LP, et al.

(b) County of Residence of First Listed Plaintiff Charles County
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) Attorneys *(Firm Name, Address, Email and Telephone Number)*
Anapol Weiss -One Logan Square, 130 N. 18th Street, Suite 1600
Phila., PA 19103
tfinken@anapolweiss.com; 215-735-1130

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC 1332 (Diversity)

Brief description of cause:
Severe and permanent personal injuries caused by the defendants' proton-pump inhibitor

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Claire C. Cecchi DOCKET NUMBER 2:17-md-2789-CCC-MF

DATE
10/18/2018

SIGNATURE OF ATTORNEY OF RECORD
/s/ Tracy A. Finken

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____